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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,265	09/05/2001	Keiko Yamasaki	2001-1026A	3583

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[REDACTED] EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/914,265 Isis Ghali	YAMASAKI ET AL. Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 September 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The receipt is acknowledged of applicants' preliminary amendment, filed 09/05/2001.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Particular humectants and cross-linking agents are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification discloses particular categories of humectants as polyhydric alcohol and superabsorbent resin and particular cross linking agents that is aluminum

compounds, does not reasonably provide enablement for humectants as a whole or cross linking agents as a whole.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 1 is broad as it recites "humectants" and "cross linking agents". Humectants can read on many categories or chemical compounds such as polyhydric alcohol as well as water. Cross-linking agents can read on chemical cross-linking, UV or heat cross-linking. Furthermore, the expression "containing" is ambiguous and unclear if the drug-containing base is made of adhesive gel or it contains an adhesive gel as one of its ingredients.

Regarding claims 2, 3, and 6, the phrase "kind of" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "kind of"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 5,725,874 ('874) or US 5,173,302 ('302) each standing by itself or in combination with US 6,455,066 (066).

US 874 teaches a percutaneous preparation comprising 0.01 to 20% of a drug; water soluble polymer; water; humectants selected from categories disclosed by applicants, i.e. polyethylene glycol, propylene glycol, butylenes glycol, glycerol, and sorbitol; and cross linking agents (abstract; col.3, lines 28-30, 66-67; col.4, lines 1-2,

14). The dosage form of the preparation can be in the form of reserve patches that have a support (abstract; col.3, line 37; col.4, line 47). The drug to be delivered in the percutaneous preparation includes anti-inflammatory agents selected from diclofenac, ketoprofen, flurbiprofen, flebinac, and indomethacin; and local anesthetic such as lidocain, benzocaine, and procaine (col.2, lines 60-63; col.3, lines 11-12; col.4, line 66 till col.5, line 2).

US '302 teaches a hydrogel formulation useful as adhesive reservoir for transdermal drugs comprises water soluble polymer; cross-linking agent; water; humectants; and at least one active agents including analgesics and anesthetics (abstract; col.1, lines 6-39; col.3, lines 28-31, 54-55; col.4, lines 3, 20-21). The patch has a backing material (col.2, lines 46-67, 64-67).

The references, however, do not teach the combination of both analgesic and anesthetic. It is within the skill in the art to combine two drugs that each one is known to have the same effect in order to have a synergistic effect. US '302 discloses at least one active agent.

US '066 discloses a transdermal patch comprising a backing and reservoir comprising hydrophilic polymer like gelatin; water; aluminum salts; one of glycerin, sorbitol, polyethylene glycol or propylene glycol; and anesthetics an analgesics and mixtures thereof (abstract; col.5, lines 8-44; col.6, lines 26, 40-44, 59-61; col.7, lines 1-3; col.8, lines 4-9, 25-29). Note: Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the transdermal patch of any of US '874 or US '302 and include a combination of analgesics and anesthetic in the reservoir, with reasonable expectation of success of the delivered patch to relief pain. Motivation would arise from the general knowledge in the art that analgesics and anesthetics both act in synergism to relief pain, or from the teaching of US '066 that the meaning of "local anesthetic" also encompasses non-narcotic analgesics.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
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